



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3815]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment Registration and Device Listing for Manufacturers and Importers of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0625. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Establishment Registration and Device Listing for Manufacturers and Importers of Devices--

### 21 CFR Part 807, Subparts A Through D

#### OMB Control Number 0910-0625--Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and implementing regulations in 21 CFR part 807, subparts A through D (part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information. Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) identification of establishments producing marketed medical devices; (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency; (3) facilitation of recalls for devices marketed by owners and operators of device establishments; (4) identification and cataloging of marketed devices; (5) administering postmarketing surveillance programs for devices; (6) identification of devices marketed in violation of the law; (7) identification and control of devices imported into the country from foreign establishments; and (8) scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System (FURLS). Burden estimates are based on recent experience with the medical device registration and listing program, electronic system operating experience, and previous data estimates.

In the *Federal Register* of February 8, 2022 (87 FR 7187), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section; Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours <sup>2</sup>
807.20(a)(5) <sup>3</sup> ; Initial submittal of manufacturer information by initial importers	4,125	1	4,125	1.75	7,219
807.20(a)(5) <sup>4</sup> ; Annual submittal of manufacturer information by initial importers	4,125	1	4,125	0.1 (6 minutes)	413
807.21(a) <sup>3</sup> ; Creation of electronic system account	5,355	1	5,355	0.5 (30 minutes)	2,678
807.21(b) <sup>4</sup> ; Annual request for waiver from electronic registration & listing	1	1	1	1	1
807.21(b) <sup>3</sup> ; Initial request for waiver from electronic registration & listing	1	1	1	1	1
807.22(a) <sup>3</sup> ; Initial registration & listing	5,355	1	5,355	1	5,355
807.22(b)(1) <sup>4</sup> ; Annual registration	28,496	1	28,496	0.5 (30 minutes)	14,248
807.22(b)(2) <sup>4</sup> ; Other updates of registration	2,671	1	2,671	0.5 (30 minutes)	1,336
807.22(b)(3) <sup>4</sup> ; Annual update of listing information	26,871	1	26,871	0.5 (30 minutes)	13,436
807.22(b)(4) Changes to listing information (outside of annual listing requirement period):					
Voluntary reporting of transfer of 510(k) clearance (outside of annual listing requirement period)	4,080	1	4,080	0.25 (15 minutes)	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
807.26(e) <sup>4</sup> ; Labeling & advertisement submitted at FDA request	9	1	9	1	9
807.34(a) <sup>3</sup> ; Initial registration & listing when electronic filing waiver granted	1	1	1	1	1
807.34(a) <sup>4</sup> ; Annual registration & listing when electronic filing waiver granted	1	1	1	1	1
807.40(b)(3) <sup>4</sup> ; Annual update of U.S. agent information	6,101	1	6,101	0.5 (30 minutes)	3,051
807.40(b)(2) <sup>4</sup> ; U.S. agent responses to FDA requests for information	1,535	1	1,535	0.25 (15 minutes)	384
807.41(a) <sup>4</sup> ; Identification by foreign establishments of importers, defined in 807.3, of the establishment's devices	14,017	1	14,017	0.5 (30 minutes)	7,009
807.41(b) <sup>4</sup> ; Identification of other importers (defined in 807.3(x)-(y)) that facilitate import by foreign establishments	14,017	1	14,017	0.5 (30 minutes)	7,009
Total					71,303

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Totals are rounded to the nearest whole number.

<sup>3</sup> One-Time Burden--Firm only provides initially.

<sup>4</sup> Recurring Burden--Firm is required to review annually.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
807.25(d) <sup>2</sup> ; Labeling and advertisements available for review	17,032	4	68,128	0.5 (30 minutes)	34,064
807.26 <sup>2</sup> ; List of officers, directors, and partners	33,851	1	33,851	.25 (15 minutes)	8,463
Total					42,527

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Recurring burden--Firm is required to keep records.

Our estimates for creating new user accounts under § 807.21(a) are based on the recent number of owners or operators. An owner or operator only creates an account one time when they register for the first time (initial registration). Once the account is created, the owner or operator uses the account as long as the establishment is registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered. Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

The draft guidance entitled “Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers” (December 2014), which contained instructions for the proposed voluntary information collection, has recently been withdrawn. While notification of transfer of ownership information is not currently required, our medical device registration and listing website<sup>1</sup> communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA’s databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

<sup>1</sup> <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>.

We estimate that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). We assume it will take 15 minutes for each listing, for a total reporting burden of 1,020 hours.

We estimate 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. We determined our estimate by identifying the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy, we assume it takes respondents an average of 4 hours to establish the transfer of a 510(k) clearance.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators maintain a historical file containing the labeling and advertisements in use. The estimate for § 807.26 reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such records current.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. When they review the importer information annually, they simply verify

the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,430 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last 3 years.

Dated: June 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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